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EXAMINER	
FORMAN, BETTY J	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,836	WERNER ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *31-42,50-64 and 67-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30,43-49,65 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *03 June 2002* is: a)☐ approved b)☒ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2/03; 3/02*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, Claims 1-30, 43-49 and 65-66 in papers filed 25 July 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Drawings

2. New corrected drawing Fig. 23 is required in this application because the replacement Fig. 23 submitted on 3 June 2002 is deemed not acceptable by the examiner. The replacement drawing Fig. 23 submitted on 3 June 2002 amends the figure to illustrate additional features the disc at the bottom of the figure. There additional features were not present in the application as filed and therefore introduce new matter into the specification.

Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-30, 43-49 and 65-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-5, 11-30, 43-49 and 65 are indefinite because the claims are drawn to an optical bio-disc. However, the structural limitations of the claims do not include any optical components. Therefore, it is unclear whether the claimed bio-disc is an optical bio-disc as recited in the preamble of the claim.

b. Claims 1-5 and 65 are indefinite in Claim 1 for the recitation "so that said reactive group attaches to said active layer to immobilize said strand of DNA in a target zone disposed between said center and said outer edge" because the recitation describes characteristics of the reactive group but the recitation does not describe immobilized DNA. Therefore, it is unclear whether the bio-disc comprises immobilized DNA.

c. Claims 6-10 and 66 are indefinite in Claim 6 for the recitation "so that said reactive group attaches to said active layer to thereby immobilize said strand of DNA" because the recitation describes characteristics of the reactive group but the recitation does not describe immobilized DNA. Therefore, it is unclear whether the surface assembly comprises immobilized DNA.

d. Claims 11-15 and 65 are indefinite in Claim 11 for the recitation "so that said reactive group attaches to said active layer to thereby immobilize said strand of DNA" because the recitation describes characteristics of the reactive group but the recitation does not describe immobilized DNA. Therefore, it is unclear whether the bio-disc comprises immobilized DNA.

e. Claims 16-20 are indefinite in Claim 16 for the recitation "so that said amino group attaches to said active layer to thereby immobilize said strand of DNA" because the recitation

describes characteristics of the reactive group but the recitation does not describe immobilized DNA. Therefore, it is unclear whether the bio-disc comprises immobilized DNA.

f. Claims 21-25 and 65 are indefinite in Claim 21 for the recitation "a reactive group which attaches to said active layer" because the recitation describes characteristics of the reactive group but the recitation does not describe immobilized DNA. Therefore, it is unclear whether the bio-disc comprises immobilized DNA.

g. Claims 26-29 and dependent Claims 30 and 65 are each indefinite for the recitation "a reactive group that attaches to said active layer to immobilize said strand" because the recitation describes characteristics of the reactive group but the recitation does not describe immobilized DNA. Therefore, it is unclear whether the bio-disc comprises immobilized DNA.

h. Claims 26-29 and dependent Claims 30 and 65 are each further indefinite in the last paragraph for the recitation "a DNA sample to be tested.....in the DNA sample" because the recitation describes a function of the input site and flow channel but does not describe structural components of the disc. Therefore, it is unclear what structural limitations are intended by the recitation.

i. Claim 30 is indefinite because the claims recite an intended use for the bio-disc i.e. directing electromagnetic energy toward the target zone and analyzing energy returned. However, it is unclear how or whether the intended use limits the structural components of the bio-disc.

j. Claims 43-49 and 65 are indefinite in Claim 43 for the recitation "said reactive group attaches to said active layer to immobilize said strand of DNA" because the recitation describes characteristics of the reactive group but the recitation does not describe immobilized DNA. Therefore, it is unclear whether the bio-disc comprises immobilized DNA.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-4, 6-9, 21-24, 43-46 and 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Hammock et al (U.S. Patent No. 6,395,562, filed 4 September 1998).

Regarding Claim 1, Hammock et al disclose an optical bio-disc comprising a substantially circular substrate having a center and an outer edge, an active layer associated with the substrate (e.g. photoactivatable biotin) and a strand of DNA including a reactive group (e.g. avidin) which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 4, lines 21-36 and Column 6, lines 11-22).

Regarding Claim 2, Hammock et al disclose the disc wherein the DNA is a single strand (Column 6, lines 11-22 and 49-50).

Regarding Claim 3, Hammock et al disclose the disc wherein the DNA includes a double strand i.e. when the oligonucleotide is hybridized to its complementary DNA (Column 6, lines 11-22 and 49-50).

Regarding Claim 4, Hammock et al disclose the disc wherein the active layer is formed from a modified polystyrene (Column 4, lines 58-61).

Regarding Claim 6, Hammock et al disclose a surface assembly comprising a substrate, an active layer associated with the substrate (e.g. photoactivatable biotin) and a strand of DNA including a reactive group (e.g. avidin) which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 4, lines 21-36 and Column 6, lines 11-22).

Regarding Claim 7, Hammock et al disclose the disc wherein the DNA is a single strand (Column 6, lines 11-22 and 49-50).

Regarding Claim 8, Hammock et al disclose the disc wherein the DNA includes a double strand i.e. when the oligonucleotide is hybridized to its complementary DNA (Column 6, lines 11-22 and 49-50).

Regarding Claim 9, Hammock et al disclose the disc wherein the active layer is formed from a modified polystyrene (Column 4, lines 58-61).

Regarding Claim 21, Hammock et al disclose an optical bio-disc comprising a substrate having encoded information associated therewith, said information being readable by a disc drive assembly (Column 3, lines 44-64; a target zone associated with the substrate and disposed at a predetermined location (Column 5, lines 1-20); an active layer associated with the target zone and a strand of DNA including a reactive group which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 4, lines 21-36 and Column 6, lines 11-22). Hammock et al further teach the information is readable utilizing software and personal computer whereby the disc is rotationally positioned during use (Column 3, line 65-Column 4,line 6 and Example 4, Column 9, lines 40-48). While Hammock et al teach the software and personal computer rotationally position the disc, the functional language "to control rotation of the disc" recited in the claim does not limit the structural components of the claimed disc.

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120

USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114).

Regarding Claim 22, Hammock et al disclose the disc wherein the DNA is a single strand (Column 6, lines 11-22 and 49-50).

Regarding Claim 23, Hammock et al disclose the disc wherein the DNA includes a double strand i.e. when the oligonucleotide is hybridized to its complementary DNA (Column 6, lines 11-22 and 49-50).

Regarding Claim 24, Hammock et al disclose the disc wherein the active layer is formed from a modified polystyrene (Column 4, lines 58-61).

Regarding Claim 43, Hammock et al disclose an optical bio-disc comprising a substrate having a center and an outer edge, said substrate having a top and a bottom surface, a reflective layer formed on the bottom surface, an active layer associated with the substrate and reflective layer (Column 4, lines 7-20) and a strand of DNA including a reactive group (e.g. avidin) which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 4, lines 21-36 and Column 6, lines 11-22).

Regarding Claim 44, Hammock et al disclose the disc wherein the DNA is a single strand complementary to a strand of target DNA (Column 6, lines 11-22 and 49-50). The recitation "which includes a reporter that is detectable by said interrogation beam" describes characteristics of a target strand but does not describe structural components of the bio-disc. As such, the recitation does not further limit the claim.

Regarding Claim 45, Hammock et al disclose the disc wherein the DNA includes a double strand i.e. when the oligonucleotide is hybridized to its complementary DNA (Column 6, lines 11-22 and 49-50).

Regarding Claim 46, Hammock et al disclose the disc wherein the active layer is formed from a modified polystyrene (Column 4, lines 58-61).

Regarding Claim 49, Hammock et al disclose the disc wherein the reflective layer is interposed between the substrate and the active layer (Column 4, lines 7-20).

7. Claims 16-19, 65 and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by Hammock et al (U.S. Patent No. 6,395,562, filed 4 September 1998) as defined by Sigma (Products for Life Science Research, 2000, page 302).

Regarding Claim 16, Hammock et al disclose an optical bio-disc comprising a substantially circular substrate having a center and an outer edge, an active layer associated with the substrate (e.g. photoactivatable biotin) and a strand of DNA including a reactive group (e.g. avidin) which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 4, lines 21-36 and Column 6, lines 11-22). wherein the reactive groups is avidin (Column 4, lines 29-36) and Sigma defines avidin as being an amino reactive group (page 302). Therefore, Hammock et al disclose the bio-disc as claimed.

Regarding Claim 17, Hammock et al disclose the disc wherein the DNA is a single strand (Column 6, lines 11-22 and 49-50).

Regarding Claim 18, Hammock et al disclose the disc wherein the DNA includes a double strand i.e. when the oligonucleotide is hybridized to its complementary DNA (Column 6, lines 11-22 and 49-50).

Regarding Claim 19, Hammock et al disclose the disc wherein the active layer is formed from a modified polystyrene (Column 4, lines 58-61).

Regarding Claims 65-66, Hammock et al disclose the optical bio-discs of Claims 1, 6, 21, and 43 wherein the reactive groups is avidin (Column 4, lines 29-36) and Sigma defines

avidin as being an amino reactive group (page 302). Therefore, Hammock et al disclose the bio-disc as claimed.

8. Claims 6, 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Charles et al (U.S. Patent No. 5,439,972, issued 8 August 1995).

Regarding Claim 6, Charles et al disclose a surface assembly for immobilizing DNA capture probes comprising a substrate (Column 4, lines 34-41), an active layer (Column 4, lines 42-57) and a strand of DNA including a reactive group which has an affinity for the active layers whereby the DNA is immobilized (Claim 1).

Regarding Claim 9, Charles et al disclose the assembly of Claim 6 wherein the active layer is formed from a modified polystyrene (Column 6, lines 1-30).

Regarding Claim 10, Charles et al disclose the assembly of Claim 9 wherein the polystyrene is polystyrene-co-maleic anhydride (Column 3, lines 8-14 and Column 6, lines 1-30).

9. Claims 1-4, 6-9, 11-14, 16-19, 21-24, 43-46, 65-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999).

Regarding Claim 1, Wang et al disclose an optical bio-disc comprising a substantially circular substrate having a center and an outer edge, an active layer associated with the substrate and a strand of DNA including a reactive group which has an affinity for the active

layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 3, line 55-Column 4, line 27 and Column 8, lines 10-44).

Regarding Claim 2, Wang et al disclose the disc wherein the DNA is a single strand (Column 4, lines 10-27).

Regarding Claim 3, Wang et al disclose the disc wherein the DNA includes a double strand i.e. after hybridization (Column 9, lines 42-48).

Regarding Claim 4, Wang et al disclose the disc wherein the active layer is formed from a modified polystyrene (Column 3, lines 65-67).

Regarding Claim 6, Wang et al disclose a surface assembly comprising a substrate, an active layer associated with the substrate and a strand of DNA including a reactive group (e.g. avidin) which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 3, line 55-Column 4, line 27 and Column 8, lines 10-44).

Regarding Claim 7, Wang et al disclose the disc wherein the DNA is a single strand (Column 4, lines 10-27).

Regarding Claim 8, Wang et al disclose the disc wherein the DNA includes a double strand i.e. after hybridization (Column 9, lines 42-48).

Regarding Claim 9, Wang et al disclose the disc wherein the active layer is formed from a modified polystyrene (Column 3, lines 65-67).

Regarding Claim 11, Wang et al disclose a bio-disc comprising substrate having a tracking groove formed therein (Column 11, lines 46-50) a reflective layer formed at least a portion of the substrate so that incident beam of electromagnetic energy may track along the groove (Column 11, lines 46-63) an active layer associated with the substrate and a strand of DNA including a reactive groups having affinity for the active layer (Column 3, line 38-Column 4, line 9).

Regarding Claim 12, Wang et al disclose the bio-disc wherein the strand of DNA is a single strand (Column 4, lines 10-27).

Regarding Claim 13, Wang et al disclose the bio-disc wherein the DNA includes a double strand i.e. after hybridization (Column 9, lines 42-48).

Regarding Claim 14, Wang et al disclose the bio-disc wherein the active layer is formed from a modified polystyrene (Column 3, lines 65-67).

Regarding Claim 16, Wang et al disclose an optical bio-disc comprising a substantially circular substrate having a center and an outer edge, an active layer associated with the substrate and a strand of DNA including a reactive group which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 3, line 38-Column 4, line 9) wherein the reactive groups is an amino reactive group (Column 4, lines 2-5).

Regarding Claim 17, Wang et al disclose the bio-disc wherein the strand of DNA is a single strand (Column 4, lines 10-27).

Regarding Claim 18, Wang et al disclose the bio-disc wherein the DNA includes a double strand i.e. after hybridization (Column 9, lines 42-48).

Regarding Claim 19, Wang et al disclose the bio-disc wherein the active layer is formed from a modified polystyrene (Column 3, lines 65-67).

Regarding Claim 21, Wang et al disclose an optical bio-disc comprising a substrate having encoded information associated therewith, said information being readable by a disc drive assembly to control rotation (Column 10, line 20-Column 11, line 9); a target zone associated with the substrate and disposed at a predetermined location; an active layer associated with the target zone and a strand of DNA including a reactive group which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 3, line 38-Column 4, line 9).

Regarding Claim 22, Wang et al disclose the bio-disc wherein the strand of DNA is a single strand (Column 4, lines 10-27).

Regarding Claim 23, Wang et al disclose the bio-disc wherein the DNA includes a double strand i.e. after hybridization (Column 9, lines 42-48).

Regarding Claim 24, Wang et al disclose the bio-disc wherein the active layer is formed from a modified polystyrene (Column 3, lines 65-67).

Regarding Claim 43, Wang et al disclose an optical bio-disc comprising a substrate having a center and an outer edge, said substrate having a top and a bottom surface, a reflective layer formed on the bottom surface, an active layer associated with the substrate and reflective layer (Column 10, lines 37-40) and a strand of DNA including a reactive group (e.g. avidin) which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 3, line 38-Column 4, line 9).

Regarding Claim 44, Wang et al disclose the bio-disc wherein the strand of DNA is a single strand (Column 4, lines 10-27). The recitation "which includes a reporter that is detectable by said interrogation beam" describes characteristics of a target strand but does not describe structural components of the bio-disc. As such, the recitation does not further limit the claim.

Regarding Claim 45, Wang et al disclose the bio-disc wherein the DNA includes a double strand i.e. after hybridization (Column 9, lines 42-48).

Regarding Claim 46, Wang et al disclose the bio-disc wherein the active layer is formed from a modified polystyrene (Column 3, lines 65-67).

Regarding Claims 65-66, Wang et al disclose the optical bio-discs of Claims 1, 6, 11, 21, and 43 wherein the reactive groups is an amino reactive group (Column 4, lines 2-5).

10. Claims 1-3, 6-8, 11-13, 16-18, 21-23, 26-30, 43-45, 65-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Virtanen (U.S. Patent No. 6,342,349, filed 21 July 1998).

Regarding Claim 1, Virtanen discloses an optical bio-disc comprising a substantially circular substrate having a center and an outer edge, an active layer associated with the substrate and a strand of DNA including a reactive group which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 5, lines 14-42 and Column 16, lines 51-65).

Regarding Claim 2, Virtanen discloses the disc wherein the DNA is a single strand (Column 16, lines 51-65).

Regarding Claim 3, Virtanen discloses the disc wherein the DNA includes a double strand i.e. after hybridization (Column 16, lines 51-65).

Regarding Claim 6, Virtanen discloses a surface assembly comprising a substrate, an active layer associated with the substrate and a strand of DNA including a reactive group (e.g. avidin) which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 5, lines 14-42 and Column 16, lines 51-65).

Regarding Claim 7, Virtanen discloses the disc wherein the DNA is a single strand (Column 16, lines 51-65).

Regarding Claim 8, Virtanen discloses the disc wherein the DNA includes a double strand i.e. after hybridization (Column 16, lines 51-65).

Regarding Claim 11, Virtanen discloses a bio-disc comprising substrate having a tracking groove formed therein (Column 11, lines 46-50) a reflective layer formed at least a portion of the substrate so that incident beam of electromagnetic energy may track along the groove (Column 11, lines 46-63) an active layer associated with the substrate and a strand of

DNA including a reactive groups having affinity for the active layer (Column 5, lines 14-42 and Column 16, lines 51-65).

Regarding Claim 12, Virtanen discloses the disc wherein the DNA is a single strand (Column 16, lines 51-65).

Regarding Claim 13, Virtanen discloses the disc wherein the DNA includes a double strand i.e. after hybridization (Column 16, lines 51-65).

Regarding Claim 16, Virtanen discloses an optical bio-disc comprising a substantially circular substrate having a center and an outer edge, an active layer associated with the substrate and a strand of DNA including a reactive group which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 5, lines 14-42 and Column 16, lines 51-65) wherein the reactive groups is an amino reactive group (Column 42, lines 16-17).

Regarding Claim 17, Virtanen discloses the disc wherein the DNA is a single strand (Column 16, lines 51-65).

Regarding Claim 18, Virtanen discloses the disc wherein the DNA includes a double strand i.e. after hybridization (Column 16, lines 51-65).

Regarding Claim 21, Virtanen discloses an optical bio-disc comprising a substrate having encoded information associated therewith, said information being readable by a disc drive assembly to control rotation (Column 10, line 20-Column 11, line 9); a target zone associated with the substrate and disposed at a predetermined location; an active layer associated with the target zone and a strand of DNA including a reactive group which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 5, lines 14-42 and Column 16, lines 51-65) wherein the reactive groups is an amino reactive group (Column 42, lines 16-17).

Regarding Claim 22, Virtanen discloses the disc wherein the DNA is a single strand (Column 16, lines 51-65).

Regarding Claim 23, Virtanen discloses the disc wherein the DNA includes a double strand i.e. after hybridization (Column 16, lines 51-65).

Regarding Claims 26-30, Virtanen discloses an optical bio-disc comprising a substrate having a center and an outer edge having encoded information associated therewith, said encoded information being readable by a disc drive assembly to control rotation of the disc, a target zone associated with the substrate said target zone disposed at a predetermined location relative to the center of the substrate, an active layer associated with the target zone, a strand of capture DNA including a reactive group for immobilization within the target zone, a flow channel in fluid communication with the target zone and a plurality of reporters deposited in the flow channel and a an input site in fluid communication with the flow channel for receiving sample DNA (Fig. 19 and 40).

Regarding Claim 43, Virtanen discloses an optical bio-disc comprising a substrate having a center and an outer edge, said substrate having a top and a bottom surface, a reflective layer formed on the bottom surface, an active layer associated with the substrate and reflective layer (Column 10, lines 37-40) and a strand of DNA including a reactive group (e.g. avidin) which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 5, lines 14-42 and Column 16, lines 51-65) wherein the reactive groups is an amino reactive group (Column 42, lines 16-17).

Regarding Claim 44, Virtanen discloses the disc wherein the DNA is a single strand (Column 16, lines 51-65).

Regarding Claim 45, Virtanen discloses the disc wherein the DNA includes a double strand i.e. after hybridization (Column 16, lines 51-65).

Regarding Claims 65-66, Virtanen et al disclose the optical bio-discs of Claims 1, 6, 11, 21, and 43 wherein the reactive groups is an amino reactive group (Column 42, lines 16-17).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 5, 10, 20, 25 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammock et al (U.S. Patent No. 6,395,562, filed 4 September 1998) in view of Charles et al (U.S. Patent No. 5,436,972, issued 8 August 1995) and/or Jan et al (U.S. Patent No. 6,403,368, filed 25 October 2000).

Regarding Claims 5, 20, 25 and 48, Hammock et al disclose an optical bio-disc comprising a substantially circular substrate having a center and an outer edge, an active layer associated with the substrate (e.g. photoactivatable biotin) and a strand of DNA including a reactive group (e.g. avidin) which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 4, lines 21-36 and Column 6, lines 11-22) wherein the active layer is formed from a modified polystyrene (Column 4, lines 58-61) but they do not teach the polystyrene is polystyrene-co-maleic anhydride. However, substrates comprising polystyrene-co-maleic anhydride were well known in the art at the time the claimed invention was made as taught by Charles et al and Jan et al.

Charles et al teach substrates comprising polystyrene-co-maleic anhydride (Column 6, lines 1-37) and they teach their substrates provide for direct immobilization of biological molecules (e.g. DNA) and eliminate the need for activation prior to immobilization (Column 2,

lines 26-31). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the polystyrene-co-maleic anhydride substrates of Charles et al to the modified polystyrene substrates of Hammock et al to thereby simplify immobilization by eliminating a step of activation prior to immobilization as taught by Charles et al (Column 2, lines 26-31).

Additionally, Jan et al teach substrates comprising polystyrene-co-maleic anhydride (Column 5, lines 36-40) wherein their modified substrates provide "one-step" immobilization thereby greatly reducing the time required for immobilization (Column 6, lines 12-37). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the polystyrene-co-maleic anhydride substrates of Jan et al to the polystyrene modified substrates of Hammock et al thereby providing "one-step" immobilization for the expected benefit of greatly reducing the time required for immobilization as taught by Jan et al (Column 6, lines 32-36).

Regarding Claim 10, Hammock et al disclose a surface assembly comprising a substrate, an active layer associated with the substrate (e.g. photoactivatable biotin) and a strand of DNA including a reactive group (e.g. avidin) which has an affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 4, lines 21-36 and Column 6, lines 11-22) wherein the active layer is formed from a modified polystyrene (Column 4, lines 58-61) wherein the active layer is formed from a modified polystyrene (Column 4, lines 58-61) but they do not teach the polystyrene is polystyrene-co-maleic anhydride. However, substrates comprising polystyrene-co-maleic anhydride were well known in the art at the time the claimed invention was made as taught by Charles et al and Jan et al.

Charles et al teach substrates comprising polystyrene-co-maleic anhydride (Column 6, lines 1-37) and they teach their substrates provide for direct immobilization of biological molecules (e.g. DNA) and eliminate the need for activation prior to immobilization (Column 2,

lines 26-31). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the polystyrene-co-maleic anhydride substrates of Charles et al to the modified polystyrene substrates of Hammock et al to thereby simplify immobilization by eliminating a step of activation prior to immobilization as taught by Charles et al (Column 2, lines 26-31).

Additionally, Jan et al teach substrates comprising polystyrene-co-maleic anhydride (Column 5, lines 36-40) wherein their modified substrates provide "one-step" immobilization thereby greatly reducing the time required for immobilization (Column 6, lines 12-37). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the polystyrene-co-maleic anhydride substrates of Jan et al to the polystyrene modified substrates of Hammock et al thereby providing "one-step" immobilization for the expected benefit of greatly reducing the time required for immobilization as taught by Jan et al (Column 6, lines 32-36).

13. Claims 5, 10, 15, 20, 25 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999) in view of Charles et al (U.S. Patent No. 5,436,972, issued 8 August 1995) and/or Jan et al (U.S. Patent No. 6,403,368, filed 25 October 2000).

Regarding Claims 5, 10, 15, 20, 25 and 48, Wang et al disclose a bio-disc comprising substrate having a tracking groove formed therein (Column 11, lines 46-50) a reflective layer formed at least a portion of the substrate so that incident beam of electromagnetic energy may

track along the groove (Column 11, lines 46-63) an active layer associated with the substrate and a strand of DNA including a reactive groups having affinity for the active layer (Column 3, line 38-Column 4, line 9) wherein the substrate is modified polystyrene having any one of a variety of functionalities (Column 3, line 65-Column 4, line 9) but they do not specifically teach polystyrene is polystyrene-co-maleic anhydride. However, substrates comprising polystyrene-co-maleic anhydride were well known in the art at the time the claimed invention was made as taught by Charles et al and Jan et al.

Charles et al teach substrates comprising polystyrene-co-maleic anhydride (Column 6, lines 1-37) and they teach their substrates provide for direct immobilization of biological molecules (e.g. DNA) and eliminate the need for activation prior to immobilization (Column 2, lines 26-31). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the polystyrene-co-maleic anhydride substrates of Charles et al to the modified polystyrene substrates of Wang et al to thereby simplify immobilization by eliminating a step of activation prior to immobilization as taught by Charles et al (Column 2, lines 26-31).

Additionally, Jan et al teach substrates comprising polystyrene-co-maleic anhydride (Column 5, lines 36-40) wherein their modified substrates provide "one-step" immobilization thereby greatly reducing the time required for immobilization (Column 6, lines 12-37). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the polystyrene-co-maleic anhydride substrates of Jan et al to the polystyrene modified substrates of Wang et al thereby providing "one-step" immobilization for the expected benefit of greatly reducing the time required for immobilization as taught by Jan et al (Column 6, lines 32-36).

14. Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al (U.S. Patent No. 5,922,617, issued 13 July 1999) in view of Burns et al (U.S. Patent No. 6,379,929, filed 19 November 1997).

Claims 26-29 are drawn to an optical bio-disc comprising a substrate having a center and an outer edge having encoded information associated therewith, said encoded information being readable by a disc drive assembly to control rotation of the disc, a target zone associated with the substrate said target zone disposed at a predetermined location relative to the center of the substrate, an active layer associated with the target zone, a strand of capture DNA including a reactive group for immobilization within the target zone, a flow channel in fluid communication with the target zone and a plurality of reporters deposited in the flow channel and a an input site in fluid communication with the flow channel for receiving sample DNA.

Claim 30 is further drawn to a step of detecting target DNA.

However, functional language reciting the intended use of the flow channel, input site, and reactive group and detection of target DNA do not define or describe structural components of the bio-disc.

> A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Regarding Claims 30, Wang et al teach a bio-disc an optical bio-disc comprising a substrate having encoded information associated therewith, said information being readable by a disc drive assembly to control rotation (Column 10, line 20-Column 11, line 9); a target zone associated with the substrate and disposed at a predetermined location; an active layer associated with the target zone and a strand of DNA including a reactive group which has an

affinity for the active layer whereby the reactive group attached to the active layer to immobilize a strand of DNA (Column 3, line 38-Column 4, line 9). They also teach that fluid is introduced to the substrate (Column 9, line 25-Column 10, line 19) but they are silent regarding flow channels and input sites for sample introduction. However, Burns et al teach a similar substrate (Column 3, lines 45-65) wherein their device further comprises a flow channel, plurality of reporters and an input site for receiving DNA sample to analyzed (Column 60, line 25-Column 61, line 390 wherein the input site and flow channel function to maintain fluid transport and keep components in fluidic communication as desired (Column 5, lines 14-35). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the input site and flow channels of Burns et al to the fluid introduction of Wang et al to thereby maintain fluid transport and keep components in fluidic communication as desired as taught by Burns et al (Column 5, lines 14-35).

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 11-15 and 21-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-66 of copending Application No. 10/086,941. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to optical bio-disc comprising very similar elements and differ only in the arrangement of the limitations. For example, instant Claim 11 is drawn to bio-disc comprising a strand of DNA while Claim 29 of the '941 application is drawn to a bio-disc comprising a capture agent and dependent Claim 30 is drawn to a DNA capture agent. As such, both sets of claims are drawn to bio-disc having the same and/or very similar scope. Therefore the sets of claims are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this

application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
September 16, 2003